**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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**IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION**

**CIVIL ACTION NUMBER: 19-md-02875-RBK-JS**

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**STATUS CONFERENCE**

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
August 14, 2019
Commencing at 2:09 p.m.

**B E F O R E:** **THE HONORABLE JOEL SCHNEIDER, UNITED STATES MAGISTRATE JUDGE**

**A P P E A R A N C E S:**

MAZIE SLATER KATZ & FREEMAN, LLC
BY: ADAM M. SLATER, ESQUIRE
103 Eisenhower Parkway
Roseland, New Jersey 07068
For the Plaintiff

GOLOMB & HONIK, P.C.
BY: RUBEN HONIK, ESQUIRE
1835 Market Street, Suite 2900
Philadelphia, Pennsylvania 19103
For the Plaintiff

KANNER & WHITELEY, LLC
BY: CONLEE S. WHITELEY, ESQUIRE
701 Camp Street
New Orleans, Louisiana 70130
For the Plaintiff

Carol Farrell, Official Court Reporter
cfarrell.crr@gmail.com
856-318-6100

Proceedings recorded by mechanical stenography; transcript produced by computer-aided transcription.

**A P P E A R A N C E S (Continued):**

KIRTLAND & PACKARD LLP
BY: BEHRAM V. PAREKH, ESQUIRE
1638 South Pacific Coast Highway
Redondo Beach, California 90277
For the Plaintiff

GOLDENBERG LAW, PLLC
BY: MARLENE J. GOLDENBERG, ESQUIRE
800 Lasalle Avenue, Suite 2150
Minneapolis, Minnesota 55402
For the Plaintiff

DUANE MORRIS LLP
BY: SETH A. GOLDBERG, ESQUIRE
BY: BARBARA A. SCHWARTZ, ESQUIRE
30 South 17th Street
Philadelphia, Pennsylvania 19103
For the Defendants, Prinston Pharmaceuticals, Solco Healthcare U.S. LLC, and Zhejiang Huahai Pharmaceuticals Ltd.

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI LLP
BY: CLEM C. TRISCHLER, ESQUIRE
BY: JASON M. REEFER, ESQUIRE
One Oxford Centre, 38th Floor
Pittsburgh, Pennsylvania 15219
For the Defendant, Mylan Pharmaceuticals Inc.

GREENBERG TRAURIG LLP
BY: VICTORIA DAVIS LOCKARD, ESQUIRE
BY: BRIAN H. RUBENSTEIN, ESQUIRE
BY: STEVEN M. HARKINS, ESQUIRE
3333 Piedmont Road, NE, Suite 2500
Atlanta, Georgia 30305
For the Defendants, Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Actavis LLC, and Actavis Pharma, Inc.

HARDIN, KUNDLA, MCKEON, POLETTO & POLIFRONI, PC
BY: JANET LYNN POLETTO, ESQUIRE
BY: ROBERT ELMORE BLANTON, JR., ESQUIRE
673 Morris Avenue
Springfield, New Jersey 07081
For the Defendant, Hetero USA Inc.

**A P P E A R A N C E S (Continued):**

CIPRIANI & WERNER, P.C.
BY: JESSICA M. HEINZ, ESQUIRE
450 Sentry Parkway
Blue Bell, Pennsylvania 19422
For the Defendants, Aurolife Pharma LLC and Aurobindo Pharma USA, Inc.

KIRKLAND & ELLIS LLP
BY: ALEXIA R. BRANCATO, ESQUIRE
601 Lexington Avenue
New York, New York 10022
For the Defendants, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd.

FALKENBERG IVES LLP
BY: MEGAN A. ZMICK, ESQUIRE
30 N. Lasalle Street, Suite 4020
Chicago, IL 60602
For the Defendant, Humana Inc.

(PROCEEDINGS held in open court before The Honorable Joel Schneider, United States Magistrate Judge, at 2:09 p.m.)

THE COURT: Good afternoon, everyone. Please be seated. Welcome.

We are on the record in the Valsartan matter, Docket Number 19-2875.

I would just ask whoever is going to speak for the parties, if you could jut say your name so the court reporter knows who's talking.

I just want to let you know at approximately 3:00, we'll have to take a short break for a short criminal proceeding. It just came in. It won't take long, but it's something we have to do. But I didn't want to hold this up, so we'll just get going. Okay?

I have your letters. I read your letters, of course. If, as I predict correctly, you made some progress in the morning when you met and conferred, and we'll talk about that.

Two general issues to talk about today: The core discovery disputes and the insurance disclosure disputes, but before that, I just want to see if we can just address a couple of housekeeping matters.

The service on the companies pursuant to the Hague, is that done or close to being done?

MS. GOLDENBERG: This is Marlene Goldenberg for the plaintiffs. And we, unfortunately, are still roughly in the

same place that we were last month. When we contacted the agencies about starting international process service, they told us that their time estimate was close to a year for most of the entities. So, you know, they've -- the wheels are in motion and things are going as quick as we can, but it gets a bit out of our hands at this point.

THE COURT: Which are the companies again that have to be served?

MS. GOLDENBERG: It's generally the four API manufacturers, so it's the Aurobindo API, the Mylan API -- if I'm getting any of this wrong, please someone correct me -- and I think --

MR. SLATER: Hetero.

MS. GOLDENBERG: Hetero, as well.

THE COURT: So, I know we have ZHP is an API manufacturer. Are they the only API manufacturer who is in the case now at the moment?

MR. SLATER: Torrent is basically in. We have an agreement that we just have to formalize something, but they have agreed to be in and they'll accept service.

THE COURT: They are an API manufacturer?

MS. BRANCATO: Your Honor, this is Alexia Brancato on behalf of Torrent.

MR. SLATER: Oh, I didn't realize you said API. I just thought we were talking about --

THE COURT: Yes, just talking about API.

Is ZHP the only API manufacturer who is in the case?

MS. GOLDENBERG: Yes.

MR. HONIK: That's right.

THE COURT: Okay. So it's out of your hands; you just have to wait for the authorities to do what they have to do?

MS. GOLDENBERG: Unfortunately, yes.

THE COURT: Okay. Everything on track for the MDL application in September?

MR. HONIK: Yes. We anticipate that will be on file sometime next week.

THE COURT: Okay. And --

MR. HONIK: Yes.

THE COURT: So by now you probably know what you're going to ask for. You're going to ask for the addition of the third chemical and all sartans; am I right about that?

MR. HONIK: The last -- Judge, the last draft of it that I saw just included losartan and irbesartan. You raise a good question about whether it should speak to the new chemical. We'll certainly --

THE COURT: I thought we talked about this the last time.

MR. HONIK: I apologize. I was not here at the last case management conference, but we'll confer internally.

THE COURT: My recollection is -- the record will speak for itself -- that the application was going to be for all sartans and not just the two you mentioned. Am I wrong about that?

MR. SLATER: That was the discussion, your Honor, to capture any contaminated sartans, any sartans with a contamination.

THE COURT: But I just want to know what's going to be presented to the panel.

MR. HONIK: We'd like to style it in a way that captures all contaminated sartans.

THE COURT: Okay. I spoke to Judge Kugler. He's out this week in Washington, saving us from terrorists. He's going to respond to the motion-to-dismiss letters next week, he said, when he gets back.

My notes indicate the short-form complaint was due I think today, so we'll get that and we'll enter that. Am I right about that?

MS. GOLDENBERG: Yes, your Honor. You have it in your e-mail, I hope. Otherwise, I'm happy to send it again.

THE COURT: Today?

MS. GOLDENBERG: I'm sorry?

THE COURT: When was it sent?

MS. GOLDENBERG: During -- or right before the last hearing. I'm happy -- I can send it again.

THE COURT: The final version?

MS. GOLDENBERG: Yes. But, actually, in light of the order that you issued over lunch where you renumbered the case management orders, I was going to point out that it now needs to be CMO 12 anyway --

THE COURT: I'll change that.

MS. GOLDENBERG: -- so I'll resend it.

THE COURT: Okay. Could you do me a favor, resend it? I don't recollect seeing that.

MS. GOLDENBERG: Not a problem, yes.

THE COURT: That's why it hasn't been entered yet.

Okay. And I know the defendants are concerned about this. Are we on track to finalize the plaintiffs' fact sheets by the end of the month?

MS. LOCKARD: Yes, your Honor. Victoria Lockard for Teva and the Executive Committee. We are on track. We anticipate submitting a finalized version next week that incorporates your Honor's rulings.

THE COURT: Terrific.

MS. LOCKARD: If we can get that entered and set the clock running on the target date of August 28th, I think that's what we anticipate. And then it's just a matter of how much time the plaintiffs would be allowed to respond. At the last conference, we proposed 30 days, and then there was some discussion for a little longer. Has your Honor come to any

conclusion on that?

THE COURT: Well, I know 30 days is too short. What did we do in Benicar? Was it 60 or 90 days? I don't remember.

MR. PAREKH: Your Honor, for the initial set, it was 90, and then it was 60 going forward. So for people who had filed as of prior to the date the PFS was entered, they got 90 days to respond, and then anybody who filed after that point had 60 days from, I believe, the initial service of the complaint.

THE COURT: Okay. Do you have any objection to that?

MS. LOCKARD: So, we have right now -- I don't know how many plaintiffs there were pending at that time in the Benicar MDL. We have, I think, around 125 cases currently in the MDL; not all of those are personal injury cases. So, given the -- which I believe is a smaller number, we would -- we would expect that that could be completed in 60 days in this case, and then going forward 60 days as well, just because I think we're at the outset of this litigation, and so the numbers -- the short form, for example, hasn't been entered, so we don't have a backlog of plaintiffs, you know, 500, 600 plaintiffs that this needs to be completed for.

THE COURT: Let's go with the 90/60. I don't think the defendants are going to be prejudiced in any material respect. I'll dig out the Benicar order and basically enter

the same language that we entered there. It worked well. And we'll probably also mirror the same order-to-show-cause procedure we used which worked so well in Benicar, that protects your interests, and we'll get the ball rolling on plaintiffs' discovery.

MS. LOCKARD: Okay. We'll submit a proposed order then, along with the plaintiff fact sheet, that incorporates that procedural process for the show cause.

Now, with just one point of clarification. So what we're submitting in our -- certainly, will get entered -- is the personal injury plaintiffs' fact sheets --

THE COURT: Yes.

MS. LOCKARD: -- so there are additional for medical monitoring, consumer fraud plaintiffs, and the TPP plaintiffs, which we need a little more time to --

THE COURT: The class reps.

MS. LOCKARD: -- finalize the reps.

THE COURT: Just the class reps, right?

MS. LOCKARD: Right. So that will be a separate submission.

THE COURT: No problem.

MS. LOCKARD: But we would like to get the personal injury rolling.

THE COURT: Yes, no problem.

MS. LOCKARD: Thank you.

THE COURT: Okay. So you'll prepare the order, a draft order that accompanies the fact sheet?

MS. LOCKARD: Yes.

THE COURT: Okay. And I'm sure you'll run it by plaintiffs, and if you just mirror Benicar, that's fine with us.

MS. LOCKARD: Understood.

THE COURT: Okay. I think those are the background issues I wanted to cover.

So two general issues: The core discovery and the insurance disclosure.

And, as I see it, the core discovery is divided into two parts, what I call the macro issues, the issues that apply to all defendants, and then there may be issues specific to particular defendants. Why don't we deal with what I call the macro issues, the issues, disputes, et cetera, that apply to all the defendants.

Plaintiff, you raised the dispute. We'll hear from the defendants and we'll see if we can get it resolved. I have all the papers in front of me.

MR. SLATER: Maybe the first thing to do would be to confirm what we discussed before we came in, probably make sense, right?

MR. GOLDBERG: Sure.

MR. SLATER: I'll try to recite it, if you want, and

you guys can correct me if I miss anything.

We had a good meeting today in the morning, your Honor, here in the courtroom. Thank you for letting us have the courtroom. It was very helpful. And then we spoke a little after lunch, based on the discussion.

So, I think we've reached agreement that -- and these agreements apply to the core-discovery defendants -- the API manufacturers, the finished dose manufacturers, correct? That's the scope of what we're talking about, right?

THE COURT: Can I just proceed for one moment? I tried to straighten out who belongs in which category. For the API manufacturers and suppliers, I have -- and I'm not going to give the whole corporate name -- ZHP, Hetero, Mylan, and Aurobindo. Is there anyone else besides those four?

MR. SLATER: I don't believe so.

THE COURT: Okay. For the finished product/dose manufacturers, I have Teva and Torrent. Did I miss anyone?

MS. HEINZ: Yes. Aurolife.

THE COURT: Aurolife?

MS. HEINZ: Aurolife Pharma LLC.

THE COURT: Okay. Is that with an A?

MS. HEINZ: Yes.

THE COURT: Okay. Aurolife is a finished --

MS. HEINZ: Jessica Heinz. I apologize, your Honor.

THE COURT: Okay. They are in the finished dose

category?

MS. HEINZ: They are a finished dose.

MS. LOCKARD: And, your Honor, Actavis is a related Teva entity, also finished dose. I just want to make sure that's -- that's within the Teva umbrella.

MS. GOLDENBERG: If you want, your Honor, I've got a full list of everyone.

THE COURT: Why don't you give it to me?

MS. GOLDENBERG: Okay.

THE COURT: Read it out.

MS. GOLDENBERG: So the APIs you correctly identified -- Aurobindo Pharma Limited, Hetero Drugs Limited, Hetero Labs -- I'm sorry. Hetero Drugs Limited is the API manufacturer parent corporation. The API manufacturer is Hetero Labs Limited. Mylan Laboratories Limited is an API. ZHP Limited is a manufacturer -- is an API manufacturer, and that's that group.

For finished dose manufacturers, we have Arrow Pharm (Malta) Limited.

THE COURT: Arrow Pharm?

MS. GOLDENBERG: Yes.

THE COURT: Is that different than Aurolife?

MS. GOLDENBERG: It is.

Aurolife Pharma LLC is also a finished dose manufacturer. Hetero Labs Limited is a finished dose. Mylan

Pharmaceuticals, Incorporated. Teva Pharmaceutical -- I'm sorry -- Teva Pharmaceutical Industries Limited. Torrent Pharmaceuticals Limited. ZHP is both an API and a finished dose manufacturer, so they fall into both categories. And I think that covers everyone of each.

THE COURT: So some defendants in the corporate chain might be in both categories?

MS. GOLDENBERG: I believe ZHP is the only one that falls into both, but yes. Oh, and Hetero Labs. Sorry.

THE COURT: Have all the finished product defendants, have they all been served?

MS. POLETTO: Hetero Labs Limited has not.

THE COURT REPORTER: I'm sorry. Your name?

MS. POLETTO: Janet Poletto.

THE COURT: Are they a foreign company?

MS. POLETTO: Yes, your Honor.

THE COURT: Anyone else in the finished product category?

MR. SLATER: Now my comment on Torrent would be relevant. I think we have an agreement on it. We're just putting some fine touches on it. But there is agreement that there is not going to be a service issue as to them. They haven't been served yet, but there is no issue with that.

MS. LOCKARD: And I believe Arrow (Malta) hasn't been served yet either, but they're no longer an extant company, so

that they just don't exist anymore.

THE COURT: Okay. All right. I think I interrupted you, Mr. Slater, so the floor is yours.

MR. SLATER: No problem.

So we have agreement, again, for I guess those two groups of defendants that we just identified, because they're the ones that are subject to the core discovery, that they will each provide -- or to the extent that I guess we're going to get a letter from all the defendants listing all of the API and finished dose manufacturing facilities, so that we will have those lists so we will be able to cross-reference them to other discovery, know where everything --

THE COURT: Could you be a little bit more specific? Is it going to be just for valsartan or the all sartans or is it different?

MR. SLATER: The only discussion we had was revolving around valsartan, and that's all that's been committed to by the defendants. I'm not in a position today to advocate for anything beyond that. You are. I'm not.

THE COURT: Okay. It's the API manufacturing facilities?

MR. SLATER: The API manufacturing facilities and the finished drug or finished dose manufacturing facilities.

THE COURT: Okay. So that would be -- clearly, that's relevant. That were involved with what? The recalls?

Or just made it at any time?

MR. SLATER: At any time, I think, and then, you know, I guess as we go through the case, we'll figure out which facilities are implicated.

THE COURT: They might be the same; they might not be the same?

MR. SLATER: Right.

THE COURT: Okay. So do we have to go through the same exercise if the definition, scope of the case is modified to include the other sartans or is it likely they're the same facilities?

MR. SLATER: I can't comment. I don't know. I'm sure there is some overlap and probably some difference, but the defense would know far better than we do.

THE COURT: We'll cross that bridge when we come to it, right? Okay.

MR. SLATER: So that was one agreement.

And the second one, again, as to the core discovery, defendants have agreed that they will provide us corporate organization information, and what we discussed was -- we discussed corporate organization internal to the company, like for example, take ZHP as the example. Within the company, although we didn't get into the details of that, probably have to discuss more, and obviously that's going to be part of our discovery requests anyway, our requests for documents, but the

more -- the more focused part of the conversation was we're going to be given corporate organization between the core-discovery defendants, the API and finished dose manufacturers, and their affiliates that were involved with the manufacture or sale or distribution of the valsartan, so that we will know, at least at that level, who is who, who did what. And they're actually going to -- they have committed to provide us what is the corporate relationship, for example, is it a subsidiary, and what their role was in the valsartan story.

THE COURT: Terrific.

MR. SLATER: Did they manufacture, did they distribute, did they package, whatever they did, did they sell, and we thought that was helpful. And in that context, they said we will get a list of all the ANDAs because they will tell us who owns each of the ANDAs as they go through that list of core-discovery defendants and their affiliates, so that they will make sure all the ANDAs are accounted for.

THE COURT: Which ANDAs?

MR. GOLDBERG: Again, valsartan.

MR. SLATER: For valsartan. And we discussed this a little bit. I believe it was agreed, the various valsartan drugs, not just valsartan. There is valsartan, amlodipine, hydrochlorothiazide. There is a couple of different formulations, but they all have a core of valsartan.

I think that's the -- that covers the agreements. I'll leave it to the defense to put a fine point on it, if necessary.

THE COURT: Well, I think that's great because I would definitely put all of that in the core category, and that is going to be an immense help to plaintiffs to properly frame their discovery, so that's perfect.

MR. SLATER: Not to the parts we didn't agree to?

THE COURT: (Laughs.)

MR. SLATER: One of the general issues that we discussed is -- and it was something that came from some of the e-mails with the Court, and we have discussed it with the defense, is to identify which defendants no production has been made from and why, and that goes to the custody, possession, control issue. And from our discussions, it appears that the two foreign defendants for which no production has been made are Aurobindo and Hetero, and I guess it's Hetero Labs Limited and Aurobindo -- I don't remember what comes after Aurobindo, but it's the Indian Aurobindo entity. Those are the --

MS. GOLDENBERG: Aurobindo Pharma Limited.

MR. SLATER: Aurobindo Pharma Limited.

THE COURT: These are the API manufacturers?

MR. SLATER: Yes. And Hetero is also, as we were just discussing, also a finished dose manufacturer as well.

And we discussed with counsel for the U.S. entities, who are here before the Court, for example, have you tried to get the documents from them; if somebody in your company were to send an e-mail and say, hey, send me the test results, can I take a look at them, would they do it? The conversation didn't really advance very far, so we're -- I think that's really as far as we've gotten, that there is no production from those entities, and at this point I don't think there is any contemplation -- and, of course, correct me if I'm wrong -- that there is any contemplation on the defense side of making a production for them until they're served.

THE COURT: Okay. So let's just see if we got this right, and I don't know the technical legal names of the companies, but the foreign API manufacturers, Aurobindo, Hetero, we know they haven't been served pursuant to the Hague, but do they both have -- I don't know what to call them -- American affiliates or American subsidiaries?

MR. SLATER: Yes, and both are before this Court.

THE COURT: Okay. So the legal issue would be do the American companies have "control" over the foreign companies' documents such that they can request them and the Court can order them to be produced?

MR. SLATER: That's our understanding, your Honor.

THE COURT: That's the legal issue.

So, we have, I guess, two choices. You can pursue

that avenue against the American companies now or wait until the foreign companies are served, and then they'll be subject to court jurisdiction and we can order them to produce them.

Defendants, what's your position?

MS. POLETTO: If I may, Your Honor, Janet Poletto for Hetero U.S.A.

Our position is that we are really not in a position to do any more than we have which, quite honestly, is quite substantial. We have made a substantial production of everything that Hetero USA has in its possession that relate to the ANDAs and any communications with the FDA, and there is a lot of materials in there. I believe it's close to 30,000 pages of documents that my client has incurred the expense of doing.

It is not really accessible to us in any easy way to go the next step that apparently the Court is asking. So I think it would be a burden to place on them during core discovery. They've got a lot of information in what we've produced that I think would be very helpful to the plaintiffs, and we've followed your Honor's order in doing that. But we don't believe we need to be put in a position of somehow being forced to try and get this from an entity that we do not represent, and that, yes, our company is an affiliate subsidiary, but it's a very -- it has a very limited role in what it does as the FDA liaison. So we have really extended

ourselves significantly at this point.

THE COURT: I don't know if the plaintiffs have had sufficient time to look at all the documents yet, but the documents you have received from Hetero, do they reflect communications with the foreign entity and do you have any sense at the moment whether the production evidences that at least there is a colorable argument that Hetero has control over the foreign entity?

MR. SLATER: Well, there is certainly a colorable argument because Hetero USA represents that it is the U.S. representative of the foreign entity. So the way these companies work, they're probably -- they're talking all day long, they're in touch with each other all day. It would be inconceivable that there is not a free flow of information between the companies. You know, counsel could correct me, but it couldn't -- it's inconceivable that, especially where the USA entity has documents that show they're actually in business, they're actually operating, and, obviously, we need what the foreign entity has, it would seem to us that in terms of the standard, which your Honor actually cited in your -- you've cited previously in the court for us, it would seem to us they have at least access to these documents and the ability to obtain them, and I think that's ultimately probably the question that would be the legal question.

We'd prefer it be done easily as opposed to, you

know, there could always be a corporate rep deposition of somebody. I mean, we're concerned if it takes a year, these -- you know, then we lag with those two parties, and then more discovery comes in later, it becomes somewhat staggered and it could become an issue at a later date. We don't know what's going to come from them so --

THE COURT: Do you know -- again, I don't know if you've had sufficient time to look at the documents -- if there are any categories of core documents that Hetero hasn't produced? My guess is the ANDA has been produced, but, obviously, the inspection reports are prepared and things of that sort.

MR. PAREKH: Your Honor, we have not seen any inspection reports for Hetero India. We have not seen communications between Hetero USA and Hetero India, nor would we expect to, given what was produced in core discovery.

We got some additional documents just last night that we have managed to load this morning but have not had a chance to review, so we don't know what's in that group.

But, in terms of the documents that we've seen so far, the ANDAs do not appear to be complete. They were produced in a -- in a manner that doesn't appear to be the way that the other defendants produced ANDAs in terms of they're not a cohesive -- it's not, you know, ANDAs starting with number one and going all the way down. It appears to be bits

and pieces, and we can't piece it together to know whether or not we have complete ANDAs.

THE COURT: Counsel for Hetero, let me ask you a question.

MS. POLETTO: Yes, your Honor.

THE COURT: We started out a few moments ago with what the parties agreed to, and one of the agreements was that the defendants that we're talking about are going to give a list of all API manufacturing and finish facilities and a corporate relationship between at least the key defendants. Is your client going to do that? The one you represent.

MS. POLETTO: My client, Hetero USA, has agreed to do that, yes.

THE COURT: Okay. So, in order to do that, won't you need to get information from this company in India?

MS. POLETTO: No. My client, your Honor, has the information, but it's in the documents that we've produced. We have answers to those questions in the documents we've produced, which we can tell the plaintiffs, it's in the documents, but we can use those documents to make the representations as to what those facilities are. The corporate relationships is -- it's my client's understanding of those corporate relationships.

THE COURT REPORTER: I'm sorry, I can't hear you.

MS. POLETTO: I'm sorry.

And as far as the corporate organizations, you know, that's in our corporate disclosures, and our client is aware of that.

THE COURT: Here is what I'm wrestling with, counsel. I would consider giving plaintiffs the right to take a 30(b)(6) on these possession, custody, and control issues, the nuclear option. I don't want to do that. I really don't want to do that. I think it just takes us down a rabbit hole, and there's almost guaranteed to be disputes because it's such a factual determination. But, on the other hand, I don't want to wait nine or ten or eleven months for plaintiffs to get these core documents. Been in other cases like this, and clients make a strategic decision. I don't know what the facts are going to show. I don't know what the eventual ruling is. But when you look at the benefit or burden, yes, they're not served yet, but does it make sense from a strategic point of view for the client to say I don't want to risk some judge telling me that the American company has control over the foreign company, and this and other litigation for the rest of the century, we're going to have to produce foreign documents. Why not just produce them? A lot of companies do that.

MS. POLETTO: Understood, your Honor. This is a different situation. Perhaps a company that has different relationships in other situations, I don't understand. I

don't know specifically what you're referencing. It's just -- it's not something that I can represent that we can do at this point in time.

THE COURT: What about Aurobindo?

MS. HEINZ: Jessica Heinz on behalf of Aurobindo USA and Aurolife LLC.

I might be stating the obvious here, but I think the Court is in a very bad position, and I think it's partially due to the fact that Hague service on these foreign companies wasn't initiated when suit was first filed against them. Had it been back in January, I don't think we would even be dealing with this situation right now, so I think that's something that's important to note.

And I also want to talk about how the plaintiffs are relying on -- I think they cited to a case that says the District Court of New Jersey follows this practical ability test when it comes to defining control, but from the case law that I've seen, it looks like the Third Circuit applies a more strict test in the case of, you know, Rule 34 discovery, which is called the legal rights test which basically says that the party has to have the legal right to obtain documents requested upon demand.

And it's my understanding from my client, you know, we're not just dealing with requests for documents owned by a foreign entity. This is a foreign party that we're talking

about, that they've chosen to bring into this litigation. And it's my understanding from my client that they can't get these documents from them. They won't give them to them. So I don't -- I mean, we can do discovery on discovery, but they're going to find out that they're not going to give them to us.

THE COURT: Do I take it Aurobindo has -- the U.S. company, whatever its name is, has produced core discovery?

MS. HEINZ: We have produced everything that we have, yes, and I have produced from Aurolife as well.

THE COURT: Is it too early for the plaintiffs to get their arms around what categories of core documents are missing?

MR. PAREKH: With Aurobindo, actually, they did produce full ANDAs, so that is different from the Hetero issue, and that was very helpful. We do also have FDA communications from Aurobindo. It's not -- we're not clear what is missing because it's hard to know what we don't have, but we do have more documents from Aurobindo than we do from Hetero in terms of categories.

MS. HEINZ: We have not turned over the DMF, obviously, because --

THE COURT REPORTER: Because? I can't hear you. I'm sorry.

MS. HEINZ: I'm sorry. We did not turn over -- we were asked what we didn't turn over. We didn't turn over the

DMF.

MR. HONIK: Your Honor, if I may, we would really relish the opportunity to create a factual record. I mean, many of the things we've seen in the public domain really support the idea that there is such control.

One only needs to go to Hetero's LinkedIn page, and this is what they've written about themselves. They write, and I quote: We have a significant presence in the development and marketing of finished dosages, active pharmaceutical ingredients, over-the-counter products.

It doesn't distinguish, it doesn't create a wall, legal or otherwise, between their finished dose operations and their API. And it has struck us that that wall really doesn't exist, and so we would really welcome the opportunity to conduct discovery in order to create that record and present it to the Court.

THE COURT: What would you request? A 30(b)(6) deposition?

MR. HONIK: Yes, your Honor.

THE COURT: Well, I'm going to grant that request. I'm going to draft an order. I just want Hetero and Aurobindo to know that the Court is doing this with the greatest of reluctance because this opens a door I do not want to open. I don't think it helps us advance the ball in the case. We go off on a tangent. Like I said, I have been in many other

cases where sophisticated clients weigh the risks and the benefits of voluntarily producing documents without prejudice. We can draft an order. But, again, I don't know how the Court is going to eventually rule on this, but the companies are running the risk that there is going to be an adverse decision, that may be forever binding in future cases, that they have to produce foreign documents. And that's -- some companies don't want to risk that. So, hopefully, they'll change their minds, but if not, we'll do what we have to do. We're not going to wait 10 or 11, 12 months to get these critical documents.

So I'll draft an order and give you the right to take, hopefully, limited discovery on the control issue, and then we'll set a briefing schedule and decide the issue.

Okay. Next issue?

MR. SLATER: The next issue is, again, a global issue. Your Honor, I'm referring to your order of April 24, 2019, because this issue comes right from the language in the order.

THE COURT: This is the Core Discovery Order, right?

MR. SLATER: Correct.

THE COURT: I have it right here.

MR. SLATER: Your Honor, in Paragraph 5 on Page 2, your Honor directed the defendants to identify the Bates numbers of the documents responsive to each category of

documents listed in Paragraph 6 herein. And the --

THE COURT: That's pretty self- -- I don't know how I can make it any clearer.

MR. SLATER: I could tell you how.

THE COURT: (Laughs.)

MR. SLATER: No, I'm kidding -- I'm being -- I'm kidding.

Here is the dispute. Within Paragraph 6, you have Section 3, and there is multiple categories. There is Category 1, 2, 3, 4, all the way through Category 5, 6. And what the defendants have done is they produced the documents and said the communications with the FDA are in this range. And we said, well, can you tell us where the documents are that reflect each of the categories within there, 1 through 6, and we were told we don't have to do that; you figure it out.

So we're asking that they provide us the Bates ranges. For example, I will give you an important one, Section 3, efforts to contain, remove, or detect the contamination, so that we know what they're relying on as production of that information. It would be helpful for us to know what's been produced and what's not, as opposed to trying to figure it out for ourselves.

Because one of our concerns is there may be no documents responsive to Paragraph -- to Section 1 or Section 2, but there may be 3, 4, and 5, and we don't know what they

have produced documents in response to, so we don't know if they answered all of these different sections, and we don't know what the documents correspond to.

THE COURT: Are we talking about a great volume of documents?

MR. SLATER: It's -- I can't given you the number of pages but it's -- it's somewhat significant. I mean, the overall production so far, compared to what we're ultimately going to get, is very small, so we're not talking about a lot of documents. There is really no great burden to doing this. Our view is it should have just been done in the beginning. And one of the things we said is we just want to make sure of what you've produced, what it's responsive to. And then, for example, with -- you know, testing is obviously a major focus for us, and we need to know which documents, which pages within there you're relying on as communication of test results. And we just don't have that, because, ultimately, one of the things we don't have, and -- we had asked in the meet and confer process, for example, can you tell us, A, a list of all the tests that have been done. We were told no, we're not doing that, that's not what was ordered. So then we said, well, can you at least tell us if the FDA communications that you've produced encompass all the testing that's been done relevant to this case? And we were told no, figure it out from the documents, and we don't need to tell you that.

So it left us in a bind, saying we at least need to know what you're saying you produced at this point so that when we do the, obviously, the general discovery, we ask for all the testing, we will be able to compare and see what's new because we obviously don't want to reanalyze the same data.

MR. HONIK: Your Honor, to give you a direct answer to your question, the size of the haystack of Category 3 communications among all the defendants is about 10,000 documents. 10,000. So you could see the dilemma of trying to discern, within the 10,000 or so documents, which fall into the six categories. If it was 20 documents, we wouldn't make this request, but that's a pretty big haystack. Pages. I misspoke. It's pages.

MR. GOLDBERG: Your Honor, I mean, I think one thing that all of the defendants did was identify -- when you look at your discovery order, identify the documents, by Bates range, by general category. The focus here is on 6(a)(3) and the subcategories. And one of the challenges to doing this the way they have asked is that within many of the documents that have been produced, you are going to have --

THE COURT: Multiple categories.

MR. GOLDBERG: And I'm holding examples.

THE COURT: I know.

MR. GOLDBERG: Right? And so we -- there is a, you know, there is a challenge here when plaintiffs are requesting

information, they want information, you order us to produce it, we produce it, we produce it quickly, we do what is, you know, reasonable and efficient, and plaintiffs want more guidance. I mean, they do have to review the documents.

Now, we don't want to make the judgment calls. It shouldn't be on us to determine, okay, this document is going to be listed as an ARB recall document and a communication document and a testing document. They're all there for us to -- certainly, for us to go back now and re-review, even if it's 10,000 pages or 20,000 or 30,000, is a significant burden. They have the information. And, you know, we have now told them we are going to provide them the lists that they requested. So, you know, given the lists and the general categories of information, there really isn't a lot of mystery.

THE COURT: The Court's intent when it drafted this order was for Category 1, 2, 3. The Court did not envision that Bates numbers would be -- in core discovery, would be given for 6(a)(3). So that's another way of saying plaintiffs' request is denied, to require the defendants to identify the Bates numbers specific to (3), (1) to (6). I assume they have identified the Bates numbers for (a), (1), (2), and (3).

MR. GOLDBERG: Correct, Your Honor.

THE COURT: That was the Court's intent when it

drafted the order.

Next issue?

MR. PAREKH: Your Honor --

THE COURT: Next general issue.

MR. PAREKH: The next general issue has to do with the format of the ANDA productions. And I mean, obviously, there was -- whether it was -- we don't think there was any intent on either side. This was an ambiguity. But it was our understanding that ANDAs, under the ESI protocol, are what would fall under the structured data provision of the ESI protocol, which would have required a meet and confer as to what format that they would be produced in. And the reason for that is that in the eCTD format, which is sent to the FDA, there are structure files which allow you to click through and find specific documents, know what was done through an index, and be able to tell, you know, what went into what category.

The way the defendants produced those documents was to break that structure and produce each of the files individually. The problem with that production is that at that point we can't recreate that structure, and --

THE COURT: Do you think the ANDA was produced in the format it was in in the usual course of business?

MR. PAREKH: They had to have because it's an FDA requirement that it be produced in eCTD format --

THE COURT: No, no.

MR. PAREKH: Oh, produced to us?

THE COURT: To you.

MR. PAREKH: No, absolutely not.

THE COURT: That's what I asked.

MR. PAREKH: No, it was not produced to us in the way it was kept in the ordinary course of business.

THE COURT: So we'll hear from the defendants, but is this just a matter of pushing a button and sending it out? Do you know -- we'll hear from the defendants -- will they have to go to any extra burden or expense to produce it in this format?

MR. PAREKH: What they should be able to do is copy the folder, as it was sent to the FDA, to either a hard drive or some other, you know, form, just copy it, paste -- you know, put it in there and produce it as a single Bates numbered document in its eCTD format. There should be no additional burden other than making that --

THE COURT: What's it called? eCTD?

MR. PAREKH: I'm sorry. It's a lower case "e," capital "C," capital "T" as in Tom, capital "D" as in David.

THE COURT: Can someone speak for the defendants? Is this just a matter of pressing a button and producing it?

MR. TRISCHLER: Good afternoon, Your Honor. Clem Trischler.

Unfortunately, it's not, and if I could back up a

little bit. This issue was addressed with the Court at our June status conference.

THE COURT: The ANDA?

MR. TRISCHLER: Yes. We specifically asked what format the ANDA should be produced in, and what the plaintiffs indicated on the record at that time was they wanted the ANDA files produced in accordance with the ESI protocol. No one said at the plaintiffs' table at that point in time in June these documents are submitted to the FDA using the eCTD format, a format that the FDA has used for eight -- at least eight years, as far as I know. We want you to submit it the same way. No one ever said that. And so we went to the cost and expense of producing them in accordance with the ESI protocol which included, your Honor, a review, it included confidentiality designations to make those reviews, and we didn't -- we were mindful of the Court's directive that it's not going to sanction blanket confidentiality designations, so that meant reviewing and making certain that a document was, in fact, confidential. We redacted private patient information on bioequivalency studies, redacted patients' names.

If we have to go back and reproduce the ANDA files which each one -- in Mylan's case, we produced three ANDAs for valsartan-containing medications, each one over 20,000 pages in length. If we have to go back and produce them now in

another format, giving them the same documentation that they already have, we're going to have to do that same review over again. I've talked with -- I've checked with our vendor. The review process, the information that's been coded, will be lost. We have to do it over again. That's a significant expense, and I'm happy to represent to the Court that it's an attorney expense that my client has already incurred. It's tens of thousands of dollars.

The plaintiffs, at our meet-and-confer session today, understandably, they don't want to bear that expense, but my client shouldn't have to bear the expense of doing it twice.

And so the reality of it is, your Honor, they have the documents. They have the documents in accordance -- in a form that's in accordance with the ESI protocol that we all negotiated and that we all agreed to. And I wish it were as simple as pressing a button. If it were, I think it's one of those issues that we could have resolved this morning, but it's simply not, your Honor, and for that reason, we request that the plaintiffs' proposal be rejected. Where the ANDA files have been produced in accordance with the protocol negotiated by the parties, that ought to be enough.

MR. PAREKH: Your Honor, we believe that, one, the protocol talks about structured data being produced --

THE COURT: I'm sorry. What does "structured data" mean?

MR. PAREKH: Items that are kept in a structured format, for example, in a database or in a form which is where you have an index system which makes that underlying data usable. It's not just -- these aren't just Word documents that were in a folder. These were -- these were compiled in a very specific tabular way with information that tells you where things go, in what categories, which documents fit into which categories, and how to access them.

THE COURT: Is counsel correct that this was an issue that was discussed at a prior conference?

MR. PAREKH: It was not discussed directly. The way it was discussed was are you going to produce core discovery in conformance with the ESI protocol or not? They said they were not. We said no, we want it in conformance with the ESI protocol.

THE COURT: And I think I said --

MR. PAREKH: And you said produce it in the format --

THE COURT: With the ESI protocol.

MR. PAREKH: And the issue is whether they considered this structured data or whether they didn't, but they never talked to us about it.

THE COURT: But let me ask you a question. You know, you've been involved in these cases before. You know about ANDAs. You knew or should have known that this was the format that it was submitted to the FDA. Why did you not request

defendants -- why did you not tell defendants, hey, this is the format in which we want the ANDA production?

MR. PAREKH: Because we've never gotten it in any other format. It didn't strike me -- honestly, that they would produce it -- they would go to the trouble that they did of breaking it apart and producing it in a unusable format. It just -- it didn't strike me. It seemed like -- we've gotten it in eCTD format in every other litigation. We expected them to do -- if they were going to do something else, to meet and confer with us, because that's the format in which it's regularly kept.

As to Mr. Trischler's issue in terms of the burden that they have gone to and the burden that they will have to go to again, the only defendant that had any redactions on their ANDA is Mylan. And those redactions were limited to one specific type of a file which contained patient information.

THE COURT: Is that a discrete --

MR. PAREKH: It's a discrete item --

THE COURT: -- area that --

MR. PAREKH: Yes.

THE COURT: -- you'd expect someone who knows what they're doing can segregate out?

MR. PAREKH: Absolutely. They should be able to simply take that one folder of those documents and segregate those out and say, we're not going to produce them because

they're redacted documents and you already have them. We're okay with that. We don't have a problem with that. No other defendant that we have been able to tell has redacted any portion of their ANDA file, and, therefore, we don't believe that there is this huge additional burden --

THE COURT: Were any of the ANDA productions -- was there a privilege redaction?

MR. PAREKH: There were no privilege redactions other than the redactions for confidential patient information which are technically, I guess, not privilege redactions. The confidentiality designations can be done on the entire eCTD --

THE COURT: Of course.

MR. PAREKH: -- as it was done. There is no reason why that can't be done. So we don't believe that there is any significant additional burden for them to produce it in eCTD format.

Your Honor is absolutely right. If I had thought of it, I should have brought it up. You're right. But I didn't because I've never seen it done --

THE COURT: Is there any objection to designating the entirety of the ANDA as confidential? That's done in every one of my patent cases.

MR. PAREKH: No, there is no objection.

THE COURT: So, Mr. Trischler, right back at you. Counsel is saying, one, you don't have to do redactions again

because you don't even have to produce those documents again, and he's representing that there were no privilege redactions or assertions. So what's the burden?

MR. TRISCHLER: Well, your Honor, before I address the burden, let me address the issue of what was discussed. The discussion, and the record will speak for itself, obviously, but I have a vivid recollection of our June conference, and the discussion was not about how the core discovery production was going to be produced. We specifically raised the issue of how plaintiffs wanted the ANDAs produced, and this is what we were told to do, and we did. And the answer back from the plaintiffs was produce it pursuant to the ESI protocol, and your Honor agreed. And, again, the record will speak for itself, but I don't feel like I'm going out on a limb in making that representation to the Court.

As to -- as to the issue of burden, I understand the plaintiffs' suggestion now that the entire document can simply be marked as confidential. That's one thing. I don't know, and I'll confess I don't know the intricacies of the review process all that well to say that it's a simple fact of pulling out the pages -- identifying the pages and finding the pages where there is patient information that we feel that there is an obligation to redact that private information. I don't believe it to be that easy. I know how much time it

took us to conduct a review the first time. And, in committing -- in fulfilling my fiduciary obligation to my client, I would be hesitant to produce 60,000 pages of documents without reviewing them and just taking someone's word for it that it's been done the right way.

THE COURT: Here's what I'm going to do. I'm going to order, consistent with this Court's effort to take a practical view of the litigation and the issues, if plaintiff is representing that it's not in a usable format -- we're talking about a critical document in the case -- it just makes no sense. I'm going to order that the ANDAs be produced in this eCTD format -- you can meet and confer with the plaintiffs if you want redactions, et cetera -- with this proviso: Defendants, if you believe it's necessary and appropriate, you can make an application to the Court for costs, the extra costs that you're going to incur because of this new production. Do it by motion. If there is good cause, the motion is going to be granted. We'll hear from plaintiffs. And I think that's the fairest thing. I don't disagree that, in hindsight, plaintiff should have been more specific, but I think, as a practical matter, to advance the litigation, all documents, plaintiffs' and defendants', should be produced in the usual format, and it just sounds to me like it's just not a terribly complicated process. ANDAs are produced all the time in our patent cases. There is a rule,

it has to be automatically produced, and there is never ever a problem with privilege or such. And to the extent that there is any ambiguity, I'm saying you could mark one stamp confidential, the whole ANDA is confidential. Okay?

We're going to take a short break for this criminal procedure. It shouldn't take long. And then we'll get right back.

MR. SLATER: You need us to move from counsel table, right?

THE COURT: Yes.

(A recess was taken from 3:04 p.m. to 3:42 p.m.)

THE COURT: Counsel, you can come up.

Okay. Ready, counsel? We are back on the record. Thank you for your indulgence. Those criminal proceedings come up unexpectedly and there is nothing we can do about the interruption.

We dealt with -- in terms of disputes, we dealt with the control document issue, the Bates number issue, the eCTD issue.

Before we get onto any other disputes, the information that the defendants agreed to give to the plaintiffs, have you all agreed on a date when that's going to be exchanged?

MR. GOLDBERG: No, we did not.

THE COURT: Do you want to agree on a date so we

don't have a dispute in the future? 30 days?

MR. GOLDBERG: 30 days is fine, your Honor.

THE COURT: Okay. That's great.

Okay. Mr. Slater, any other generic, general macro disputes?

MR. SLATER: We do, and I'm going to -- our team is going to participate in that, defendant by defendant.

THE COURT: Wait a minute. Are we dealing specific defendant now or are we done with what I call the macro issues?

MR. SLATER: Oh, there actually is one -- there is one issue, you're correct. Our agreement on the lists didn't determine this one issue.

Your Honor, with regard to the productions, we have a disagreement. Again, it goes to the interpretation of your Honor's order from April. And the core discovery productions per Paragraph 2 concerned the facilities that manufactured the API used in valsartan or the facilities that manufactured the finished products. The defendants have taken the position that the productions only relate to facilities where the API was manufactured, despite the language of the order, so that's an issue we need your Honor to resolve for us, as to whether the productions are only from the API manufacturer facilities or from both.

MR. TRISCHLER: Your Honor, as part of -- Clem

Trischler again. I apologize.

As part of core discovery, the defendants produced -- and we're talking about Subparagraph 5 of Paragraph 6(3) of your Honor's April order. The defendants produced correspondence with the FDA regarding 483s, Establishment Inspection Reports, CGMP reports and the like for the API manufacturing facilities, and that was based on the plain language of the Court's order which states that the production is -- should be with respect to "any facility that manufactured or supplied the API at issue."

What the plaintiffs have asked is that that be expanded to include not just the API facilities, but any facility that was responsible for the finished dose manufacturing of the product. We believe that's not core discovery. We believe it was not part of the order, and that what the plaintiffs are asking for now simply was not directed by the Court back in April which is the reason why it was not provided.

THE COURT: I think the defendants are right about this one. Paragraph 2 identified the defendants that were subject to the order. And Paragraph 6 in Sections (a) and (b) identified the specific documents for the two categories that have to be produced. And unless 6(a)(3)(5) is listed in 6(b), the finished product/dose manufacturer defendants don't have to produce it. And that appears to be the case, because, in

Paragraph 2, the Court referred specifically to 6(a)(3) and didn't list the other subnumbers of 6(a).

MR. PAREKH: So, just to be clear, the reason that we brought this up is our interpretation of 6(b)(2), where it referenced 6(a)(3), which is "Communications with the FDA," was that it's those sub- -- those categories of documents --

THE COURT: That's right.

MR. PAREKH: -- and, therefore, it didn't really make sense where -- why would the finished product/dose manufacturer have to produce communications regarding the API? We simply thought that the Court was referring to those categories but replacing "finished dose manufacturer" with the "API manufacturer."

THE COURT: I take back what I said. I think I misinterpreted my order because the "3" that you just referred to is not in parentheses. It's a general "3." So since the Court referred to the general "3," 6(a)(3), specifically, in 6(b), Mr. Trischler, tell me if I'm reading it wrong, but it seems pretty apparent that the communications in 6(a)(3) have to be produced by the finished product/dose manufacturer defendants. If you read it differently, I would like to hear your argument.

MR. TRISCHLER: I do read it differently, your Honor. My interpretation of that, and I think what we discussed is why the Court repeated for the finished dose manufacturers is

to try and address the issue of control. If you remember, we had a lot of discussion about producing documents if they were in your control. And so what 6(b)(3) is saying is that for a finished dose manufacturer, if you have these documents within your control, produce all the items in 6(a)(3), which include 483s for the facilities where the API is manufactured. It wasn't to expand it.

To give you an example, my client has a manufacturing facility in West Virginia that produces a hundred different products. If there are warning letters that relate to all those different products, that wasn't what we wanted to get into with respect to core discovery. What we wanted to get into was the when, where, and how the problem with the API arose, and so, as I interpreted the order, and as I recall our discussions, what the Court was suggesting is we know that there are some defendants that aren't in the case yet, we know that there may be issues of control, so if we can't get to the -- all the foreign API suppliers, if there are finished dose suppliers in the United States that have control over these documents, then those finished dose suppliers, under 6(b)(3), should produce the same categories of documents in 6(a)(3). That's how I -- that's how I interpreted the order. I believe that's how the defendants interpreted the order. And I believe that interpretation to be entirely consistent with our dialogue and our argument concerning what should be

included within core discovery, and, again, to interpret it otherwise would lead to opening a Pandora's Box and requiring production at this very, very early stage of litigation of all things completely unrelated to what are the core issues in this case.

THE COURT: Doesn't 6(a)(3)(5) -- isn't that limited to facilities that manufactured or supplied the APA at issue -- API at issue?

MR. TRISCHLER: Yes, that's what we're saying, yes.

THE COURT: So you're saying 6(b) would only apply if an API manufacturer and supplier defendant did not produce the responsive documents?

MR. TRISCHLER: Yes, because it says -- if I look at 6(b)(3), it says: "To the extent not produced by another responding" party, "the discovery listed in ... 6.a."

THE COURT: And the only facilities that would be subject to the production would be the facilities that manufactured or supplied the API at issue, not the facilities that made the finished product -- the finished product, period.

MR. TRISCHLER: Yes. That's our interpretation of the order, yes, sir.

THE COURT: Mr. Slater, counsel, anything different?

MR. SLATER: We just want to make sure we get it right.

THE COURT: Yes.

MR. SLATER: And it may be that Paragraph 5 is a separate entity unto itself as compared to the other -- I'm talking about Subparagraph 5.

Because, again, going to Paragraph 2 on the first page of your order, your Honor gave a blanket statement that this applies to -- shall produce core discovery concerning -- not just -- it doesn't say concerning the defendants. It says, "concerning the facilities that manufactured the API used in Valsartan or the finished products at issue." So the order encompassed both categories of facilities.

Now, if Subparagraph (5) under 6(a)(3) is read by the Court to be limited to the facilities that actually manufactured or supplied the API, and it may even be that your Honor wants to tell the defense, and we probably wouldn't have an objection to that at the core discovery level, of limiting it to Valsartan-specific reports, I don't think that anybody would argue with that on our side because it's core discovery. So if with regard to the manufacturing facilities or the -- of either the API or the finished drug, everything else would apply, but Sub (5) would apply just to the API manufacturing facility, with regard to the Valsartan. I mean, that we could accept.

THE COURT: This is an example of no good deed goes unpunished.

MR. SLATER: Never.

THE COURT: The defendants, do I take it, only produced for the API manufacturing facilities?

MR. TRISCHLER: Yes. Yes, sir.

THE COURT: Okay. Let's limit it to that. In the next two to three months, we're going to be dealing with a document request, on a general basis, Rule 26 discovery, just put this in your document request and you'll get it, you know, reasonably soon, rather than making them go back -- if I rule that way, to go back. So I think that's a good, practical way to deal with this. For the time being, let's limit it to what the defendants have produced, and in your document requests, you could ask for whatever you want regarding the finished product/dose manufacturer facilities that may be at issue in this case.

MR. SLATER: Understood.

MR. PAREKH: Can we just get one clarification? Which is that the finished dose manufacturers did produce all of the remainder of 6(a)(3) with regard to the finished product/dose manufacturing. Because 5 is the only one that limits it to the API manufacturing facility. I just want there to be no ambiguity because Mr. Trischler referred to 6(b)(3), which is -- and in the interpretation that Mr. Trischler took, it would make 6(b)(2) redundant, so we just want to make sure that the remainder of the items in

6(a)(3) were produced.

MR. TRISCHLER: And, your Honor, what I would indicate in response to that is with respect to -- with respect to Mylan, the answer is yes, everything -- all communications within all the other categories have been produced, and with the proviso of those defendants providing -- there are some defendants providing core discovery. As we know, we talked about Aurobindo, we talked about Hetero, that produced documents in their possession. You know, subject to that proviso, I think the answer to your question is yes.

MR. PAREKH: Thank you.

THE COURT: We're done with what I call the macro issues?

(No response.)

THE COURT: Okay. Are we going to go to the company-specific disputes now?

MR. SLATER: Yes, your Honor. And I think that as far as ZHP goes, I think we've resolved -- I think we've resolved the remaining issues. There are certain documents that ZHP is going to be providing us. There is a supplemental production of a design master file and -- a drug master file, excuse me -- and I think there's two inspection reports that are being provided as well, and I think we were told we would have that all by next Friday, so that -- we appreciate that.

And we just want to confirm one thing for the record. No production was made by ZHP. What we were told was that Prinston and Solco, the subsidiaries of ZHP, produced documents, and that those documents are the same documents that ZHP would have produced. Now, we just want to confirm or have defense counsel confirm for the record that anything ZHP has that would be responsive -- because that's obviously a very important API manufacturer in this case. To the extent they had any documents or have any documents that would be responsive to this order, they have all been produced through their U.S. subsidiaries. We just want to make sure there is no ambiguity on that, for obvious reasons.

MR. GOLDBERG: There is no ambiguity on that, your Honor. That's what we represented and that's what we did.

THE COURT: Next?

MR. PAREKH: So, we were able to resolve the Aurobindo issue --

THE COURT: Is that the next company --

MR. PAREKH: That is the next company on the list, your Honor.

I mean, other than the more general issue of whether or not they have to produce the Indian company documents, which we have already addressed.

THE COURT: That's the control issue.

MR. PAREKH: Control issue.

As to the Torrent defendants, we were again able to resolve --

THE COURT: Okay. Aurobindo is -- nothing to --

MR. PAREKH: No individual issues, your Honor.

THE COURT: Awesome.

Next is Torrent.

MR. PAREKH: Torrent is the next one. And this morning we were happy to be able to resolve the remainder of the Torrent issues.

THE COURT: Let's keep it going.

MR. PAREKH: The next one is the Teva defendants, and Ms. Goldenberg will deal with that one.

MS. GOLDENBERG: It's mostly good news for you, your Honor, on the Teva defendants.

Let's start with issue Number 2. On the ANDAs, I can confirm for the record that they will be supplementing their production and producing full copies of all ANDAs, both approved and not approved.

As to issue Number 3, Teva is also going to be supplementing its production, and I think they were going to talk over lunch and determine what date they could do that by, so I'll let them give you an update on that.

Issue number 4 was a global issue that we've already addressed here.

MS. WHITELEY: Can you identify the issues --

MR. SLATER: Slow down.

MS. GOLDENBERG: I'll be happy to. Yes.

All right. So issue Number 2 dealt with the full production of ANDA files. And, just to confirm for the record, Teva will be supplementing their production to ensure that we have full copies of all ANDA files, whether or not they were ultimately approved.

THE COURT: You said issue Number 2. Are you referring to Mr. Slater's August 6th letter?

MS. GOLDENBERG: Oh, sorry. I'm going off of Mr. Goldberg's letter.

THE COURT: Never mind.

MS. GOLDENBERG: And it's on Page 9 of his letter, just so we're all in the same spot. I figured out where you guys were going.

Okay. Issue 3 in Mr. Goldberg's letter, also on Page 9, was a compilation of issues but, most notably, testing information. Teva has indicated that they will be supplementing their responses and, again, I think they'll provide the Court with the date on when they can do that by. But we don't have any disputes remaining on that issue.

Issue Number 4 was a global issue that's already been dealt with. That was the 483s, the inspection reports, that we have already discussed.

Issue Number 5, they have confirmed that they have

provided us with the full customer list for both recalled and non-recalled batches, so that means we're left with issue one, so four out of five we were able to take care of.

On issue one, there is a custodian whose name I'm going to try and pronounce correctly -- Constance Truemper, T-R-U-E-M-P-E-R. What we noticed in the production was that the files that were produced seemed to have a parent e-mail associated with them and that parent e-mail was not included in the production. It's our understanding that the reason that they haven't produced this was because the document was being sent from one person in-house to another person in-house, and when I say in-house, not to an attorney, just within the company. This just seems like a nitpicky issue for us. If there is a cover e-mail, we think it should be included. We don't know what it says, but it certainly, in theory, would talk about the document that was within the scope of the core discovery.

THE COURT: So is the argument that it's irrelevant, privileged, or --

MS. LOCKARD: Your Honor, Victoria Lockard.

The argument is that it's not within the scope of the Core Discovery Order. It is an internal e-mail. I fully anticipate this will be produced, as with the --

THE COURT: One document we're talking about?

MS. LOCKARD: No. Right now I believe they

identified 52 cover e-mails. These are e-mails from a person at Teva who circulated to a distribution saying, here's the submission to FDA, see attached. I mean, it's --

THE COURT: Why don't we just make this part of the Rule 26 discovery. It's not earth shattering and --

MS. GOLDENBERG: We can live with that.

THE COURT: We will deal with all those issues together.

MS. LOCKARD: Thank you. That was our proposal as well.

And I think I can represent we will be supplementing our production with the ANDA files which we are collecting and reviewing to make sure that, you know, to the extent we've left anything out, that that has been included.

And then on the testing issue, so the concern there is that there is testing that is ongoing, and it's just not complete, the response hasn't been submitted to FDA yet, but we've represented that we will supplement that once it is complete.

THE COURT: Good.

MS. LOCKARD: Okay. Thank you.

THE COURT: Are the plaintiffs getting the supplemental FDA correspondence that the Court ordered? There is an order that says without a request for production, you have to get correspondence sent to the FDA. Have you been

getting that?

MR. PAREKH: We have not seen a supplemental production that specifically references additional correspondence from the original production date. We don't know if there is any at this point because it's such a short time from the date the documents were produced to today. But, I mean, we would expect the defendants should be complying with that. We just -- we have not received any supplemental productions of that type of document.

THE COURT: That order just mirrors what's in the patent rules because I would assume, I don't know, that there is ongoing communications between the FDA and the defendants about this issue. So, rather than you making separate document requests or relying on 26(e), which most people don't pay attention to, unfortunately, just ordered it to be produced, so in due course, you'll get it.

MR. TRISCHLER: I can say, your Honor, on behalf of the defendants, we're certainly aware of that order and endeavor to comply with it. I know that for my client, for instance, there has been production of correspondence as recently as June and July.

THE COURT: Great.

MR. TRISCHLER: Now, practically speaking, we don't always -- I know there is a seven-day requirement. We don't always get them from our client as soon as things are sent,

but we're certainly aware of the supplementation order and we'll comply with it without additional requests as soon as we learn of the correspondence.

THE COURT: Okay. Who is next after Teva?

MR. PAREKH: Mylan is next, your Honor, and we have sort of one and a half topics left with Mylan.

The main topic is whether Mylan needs to produce their ANDA, which was -- has not yet been approved by the FDA regarding valsartan. And we understand defendants' position is that it only relates to ones that are subject to the issue underneath. However, there is definitely, from what we've been able to see publicly, as well as a few of the correspondence that were produced regarding that ANDA, that part of the reason why the FDA has not approved that ANDA has to do with the contamination issue. So, without seeing the ANDA, we can't simply say, well, there is nothing in there that would impact this case.

THE COURT: So you want it -- even though it hasn't been approved, you want it because?

MR. PAREKH: Because there may be items that are contained in that ANDA such as testing results or other, you know, documents associated with that ANDA that reflect Mylan's knowledge of the contamination issue or testing that was done by Mylan regarding those issues.

THE COURT: Is that type of -- I guess it's an

application not yet approved within the scope of the core discovery?

MR. PAREKH: The Core Discovery Order does not distinguish between approved and unapproved applications.

THE COURT: I think the Court's intent was approved ANDA files. If you want to make a request under Rule 26, that's appropriate. We'll see if there is an objection. But the Court's intent was just the approved ANDA files.

MR. PAREKH: The reason why we believe that it's relevant is because there were inspections of facilities at Mylan.

THE COURT: I'm not ruling whether it was relevant or not. I'm just saying it's not within what the Court intended core discovery to be. That's all. So you have every right in the world to ask for it under Rule 26, which we're going to deal with in the next couple of months, and if Mylan objects, we'll deal with the relevancy issue.

MR. PAREKH: And then the other half of the -- the half sort of dispute is that Mylan has produced a list of customers, but only as to the specific recalled lots, and the issue is we believe that that should be produced back to 2012. There are no other defendants who have taken the position that it only is effective as to recalled lots. Mylan is the only one with that position.

THE COURT: Let me just take a look at the order real

quick.

MR. TRISCHLER: Your Honor, I don't want to interrupt your reading, but I don't think we have much of a disagreement because what we -- what we agreed to do as part of our meet and confer today is the Mylan defendants have already provided a list of API customers; we've provided, as part of the core discovery, a list of customers known to have received finished dose products subject to the recall; and what we discussed today was part of our concern with -- with respect to the order is I'm not aware of a list per se that would identify every customer going back to 2012, but what I indicated to the plaintiff that we would -- plaintiffs that we would endeavor to do is that I would go back to my client and try to identify all known distributors from 2012 to present. So we're willing to work on that. That's what we had talked about. I thought we had resolved -- agreed on that, but we wanted to put it on the record. That was sort of the one and a half items. But perhaps I'm misstating something.

MR. PAREKH: No, I think you're correct. It's just my note did not reflect that. But yes, that was the agreement, and that is -- we put it on the record. We're done on that one.

THE COURT: Good.

MR. PAREKH: The next defendant is Hetero U.S.A. They made a production last night. We are hopeful that that

production resolves all issues, but because we haven't been able to review it, that's the best representation that we can make on that one.

THE COURT: So you have leave to raise the issue with the Court at a future conference since you didn't get the documents on a timely basis.

MR. PAREKH: Okay. And I believe that concludes all the individual defendants, your Honor.

THE COURT: Are there any insurance issues?

MR. PAREKH: Ms. Goldenberg is going to address those, your Honor.

MS. GOLDENBERG: I think most of this, your Honor, is just going to be putting on the record that we have agreed to a great deal, but I want to recap and make sure there are no disagreements from the other side.

So, my understanding is that -- let's see -- Hetero Labs has not produced an insurance policy. Hetero USA, however, has agreed to produce their insurance policy. And we have already discussed the reasons that Hetero Labs is not willing to make productions at this point, because they haven't been served.

Additionally, the -- let's see -- the Mylan entities have sent complete insurance disclosures, so I think we're good on that front.

ZHP has responded that they have no insurance, and

the Solco, Prinston, Huahai entities have sent complete insurance productions.

The Teva, Aurobindo, and Torrent entities have all produced insurance policies, and they informed us earlier today that those productions were all complete, so I believe that those are fine. The only caveat is that they are checking to find out if those are claims made policies, because they only go back to 2017. As long as we get clarification on that issue, I don't think that we have a problem, but for now, we're just waiting for them to check on that issue and get back to us.

And I think if someone from defense can just provide reassurance on the record that we do have all of the insurance policies and that I have stated everything correctly, that would be helpful, but I think I've got it all right.

MS. LOCKARD: Just on behalf of Teva, I believe that's accurately stated, that we've produced all of the insurance policies. We are checking to confirm our belief that they are claims made, and if it's other than we believe, we'll let Ms. Goldenberg know.

MS. GOLDENBERG: Okay. And I believe that all of the entities, with the exception of Hetero, have produced reservation of rights letters, to the extent that they have received them. And the defendants agreed earlier during our meet and confer that if any of those arose in the future, that

they would be willing to pass those along.

THE COURT: So you haven't received any disclaimer letters yet?

MS. GOLDENBERG: I don't think so. So I guess that's a long way of saying that I think we're fine.

THE COURT: Okay. So, as long as we're together, are there any other issues that we need to address? We always start with the plaintiff, then we'll go to the defendant.

MR. TRISCHLER: Right. I think we're going to talk about the same thing.

MR. SLATER: Yeah. We've discussed, if the Court will approve it, modifying the schedule for us to serve our document requests. In part, that's been necessary because the documents are rolling in and we're still reviewing them, and part of it is just the time of year.

THE COURT: Just give me the dates.

MR. SLATER: We would like to be able to serve our document requests by the end of the month, August 30th. And then counsel told us in the hall they wanted to talk to your Honor and float a different date to provide objections because of their needs, and we don't have an objection to the date that they suggested but --

THE COURT: Let me get out my schedule.

MR. SLATER: -- I just don't know if it's going to run into the October 24 date.

THE COURT: We'll work this out.

So the current date -- okay. So plaintiff, we moved that back 15 days. When did defendants want to object?

MR. TRISCHLER: Well, we had proposed 90 days. And plaintiffs did not commit --

THE COURT: We're not talking about answers. We're just talking about objections, just objections.

MR. TRISCHLER: I understand, your Honor. What -- the position -- you know, without having seen the requests, our concern was that when we get the requests, it's difficult to formulate objections in a vacuum. I believe we have to see the documents, understand what our client has or doesn't have. For instance, how do you formulate an objection to burdensomeness until you talk to people and get information about what's available? So we certainly don't want to file boilerplate objections. That could be done in 30 days. We're hoping to do better than that. And so --

THE COURT: Let's make it 45 days. Okay? So that takes us to October 15th.

MR. GOLDBERG: Your Honor, if I may, I just want to remind the Court that for some defendants, you're talking about definitely four different sets of document requests going to four different parties. So, you know --

THE COURT: Because you represent four companies?

MR. GOLDBERG: Correct. And so we're going to be

responding on behalf of ZHP, which the document requests will look different, because they're going to be API focused and they're going to be China focused. We're going to have Prinston, the distributor. We're going to have a finished dose manufacturer response. We need to craft -- what we're trying to do is avoid boilerplate objections to the extent we can.

THE COURT: Here is what I think you should do, just like we always do. 45 days. When we get closer to the deadline, if there is good cause to extend the dates, you know they're going to be extended. If we start at 90 days, we're going to be six months down the road. So if there is good cause, there is a good reason to extend the deadlines, we will, but we're not talking about responses. We're talking about objections.

MR. GOLDBERG: Right. And what we want to do is be able to provide objections that have meaning.

THE COURT: Of course.

MR. GOLDBERG: And so, avoiding the natural response, which is, your Honor, this is just a boilerplate objection, you should overrule it.

THE COURT: You can do that in one week.

MR. GOLDBERG: Right, of course we could do that. So we're really trying -- this is not going to be -- A, it's not going to be a small number of document requests. I guarantee

that you're talking, you know, if not around a hundred, more than a hundred for each of these kinds of defendants. Just drafting alone is going to take time. So ...

THE COURT: Okay. Document requests are due August 30. Objections are due October 15th. Then we'll give the parties 45 days to meet and confer. And then we'll have, I guess, our conference in December sometime to resolve all discovery disputes. It will be set sometime in December, which means that we will have to reschedule -- the current date for the conference to address the disputes is October 23rd, so we'll move that back to December. But if we keep on extending all these deadlines, we'll never get done with this case. So, to me, this is always the most time-intensive effort in the case, and once we get through the documents and ESI, things usually go pretty smoothly, so I really want to get through this.

So I'll draft an order summarizing what we discussed. I hope Hetero and Aurobindo will reconsider their positions so we don't have to get into the 30(b)(6) deps issue but, if not, we'll do what we have to do.

Over the next couple of months, I guess we'll be working on -- you'll be working on your objections. We'll finalize all the fact sheets. The answers will start to be rolling in. Okay?

MR. SLATER: There is only one other thing to just

touch base on, which we've discussed as well with counsel, and we discussed it with the Court the last time we were here, I believe. We would like to start a meet-and-confer process with the defense regarding custodians and search terms. And I think that we really need to start to get some dates on the calendar in September to start to informally exchange -- you know, the documents we have are so -- because they're core, we don't really have a good visibility into who the people are that are going to matter. It just doesn't come from these documents. There is a few names on them, but those are really the people who are just corresponding with the FDA, so we have some regulatory names. But we really need to start to have a robust discussion and a frank off-the-record discussion, we would suggest as we did in Benicar, regarding who are the people that matter, what are the different departments, what are they called, what are the documents referred to as, what are we -- you know, what do we need so that we can start to formulate the search terms and the custodian list so we can get that teed up with the Court as well, you know, this fall. So we just would like to just start to be able to meet and, again, we would appreciate the opportunity, once we have some exchange of -- on a preliminary and foundational level with defense counsel, to -- again, to avoid a 30(b)(6) deposition, as the Court had us do in Benicar, we were perfectly fine doing it again, to sit down with knowledgeable witnesses from

the companies and talk --

THE COURT: But they weren't taken in Benicar, were they?

MR. SLATER: No. What I'm saying is we had asked for it, and your Honor said no, no, you'll meet with them informally, and it worked very well where they brought in knowledgeable -- off-the-record conversations, but knowledgeable corporate people who talked to us and told us these are the people that matter, these are the departments, here is how it worked --

THE COURT: I think your discussion is a good one. We're not going to wait -- we can't wait until December to get the custodians and search terms. We can't wait until the ESI -- well, obviously, it has to be done before the ESI and documents are produced. But there is no way we're starting this process in December to identify custodians and search terms. So what suggestions do you have, defendants, about how to move this along?

MR. GOLDBERG: I thought we had discussed this at the last conference. This very issue about interviews was raised. What we had discussed was that defendants would put together a proposed custodian list, that -- we actually didn't decide who would put together a first list of search terms. That we didn't actually --

THE COURT: Did you talk about timing? I don't

remember.

MR. GOLDBERG: No, we didn't talk about timing, except to say that we would -- that what happened in Benicar with respect to interviewing witnesses about this was something that happened at the end of a process. We don't think it is the first step in the process. And so what we thought would be something more along the lines that we would propose a list of custodians. They now have enough discovery to react to it. There can be some process there. It may be that we avoid burdening a person from coming to the court to talk about these issues among the parties. And that, you know, that can be in September and October. That can be as we're dealing with the ESI.

I mean, I think -- in light of what we've done, I think it would be fair to have them make a first list of ESI search terms but -- and we can do the list of custodians and go from there over the next, you know, four weeks, six weeks, and see where we get to.

MR. SLATER: We have no problem with defense counsel sending us a first list of custodians and why they matter. I mean, I'm sure they can provide that to us, you know, fairly quickly. We can start to formulate a list of search terms, but we don't have -- we have some documents but we don't have a lot, so there is going to be -- there is a knowledge gap at our end. But what we don't want to ultimately do is --

because it's just not practical -- is have a back-and-forth discussion between attorneys to get the information we need to define the right custodians, et cetera, because it just -- you need to be able to talk to somebody in the company and have more of a transparent discussion. Otherwise, we'll be in December, as your Honor said, or January, and that's not what anybody wants. I mean, I don't think we're saying entirely a different thing, but I think it has to be understood we're going to be able to get this information directly from someone from the company in informal, off-the-record discussions because, again, we're bypassing the 30(b)(6) process. Your Honor made it very clear how you wanted to do this, and we're perfectly fine with that, so we're not objecting to that. But we have to be able to talk to someone from the company directly and be able to have a -- more of an organic conversation where the person gives an answer -- oh, well, what does that mean? Oh, what about this? And that's how we learned what we needed to know. And, again, we only had to add, I think, one or two custodians in that other litigation, towards the end, and it was just because certain documents came out late in the process and one or two people became relevant.

MR. GOLDBERG: Just on the ESI protocol or on the search terms, what we can do is when you give us your document requests, we'll put out the first set of search terms since

you don't have the kind of documents you think would give you that, we'll respond in connection with the document requests. That may be the best thing to do. In terms of -- you know, we haven't crossed the bridge in this case yet whether 30(b)(6) depositions or informal interviews, that issue hasn't been handled --

THE COURT: No, it hasn't.

MR. GOLDBERG: I mean, we're trying to propose a process where we can hopefully avoid even getting to that bridge.

THE COURT: We may differ on this, but it seems to me that a defendant should take the first cut at the custodians and the plaintiffs should take the first cut at the search terms.

MR. SLATER: That's fine.

THE COURT: Because you know what you're looking for.

MR. SLATER: We have some idea.

And then, also, it may be helpful -- we're obviously going to ask for a lot of different corporate organizational charts in a formal way in the discovery requests. It would be helpful, when they provide us the proposed custodians, to provide those work charts that they do have, or at least something that lays out how the company --

THE COURT: Internal, as opposed to what you have agreed to exchange, sort of the corporate-wide organization?

MR. SLATER: Correct, correct. And we are obviously going to formally request things, you know, like corporate organization of the company and then -- you know, in different departments, medical affairs or clinical affairs, you know, the different quality assurance departments, all the departments that we relate, but to the extent they have that information, it may not be something we have to wait for the discovery requests to be formalized before we get that. We would just ask that they start giving that to us because, again, then we can understand what is it that we're looking for, what's the vocabulary of the different departments, and then when we do finally get to the point of being able to have a candid interaction, we can say, well, you know, what did this department do? Was testing done by this department? Who were the people in charge? Who were doing the inspections? Who were -- you know, who were crystallizing -- the obvious questions, and we can at least understand the structure that we're discussing.

THE COURT: Let me ask you a question. At least for the moment, are we dealing with the two categories of defendants that were identified in the Core Discovery Order? We're not waiving any right to take discovery -- document requests regarding the wholesalers, retailers, those people, but are we focussing on those two categories, the API people and the finished product people?

MR. SLATER: I actually hadn't really thought about that. I thought we were doing everything. But it makes sense, it makes sense to start at that level --

THE COURT: Yes. I don't disagree.

MR. SLATER: -- and then go to the next level. And I think what we're going to learn through this interaction over the next several months is -- like one of the things we're asking for, and we discussed out in the hall, is supply chain, which we talked about earlier, and your Honor said, well, then we're going to see from ZHP where did everything flow and what are the different chains all the way down to somebody's --

THE COURT: Aren't you going to get that?

MR. SLATER: We're eventually going to get that, so that help us as well to understand, and then we'll know what we want to ask of each defendant, so we have no problem with that.

THE COURT: So what about, say, you -- what about if you each exchange your first cut at a custodian and search terms list September 15th, and then meet and confer, and we'll see where we are on October 15th?

MR. SLATER: That's acceptable to us, your Honor.

THE COURT: Because doesn't it have to be finalized by December? Assuming in December we're going to resolve all discovery disputes regarding the Rule 26 ESI and document requests. Then you'll have a set, give it to the client, say

this is what we have to respond to. That's the deadline for finalizing the custodian and search term list, right? But it is a very labor intensive effort, so if we start in September, we should be done by December.

MR. SLATER: It's the only way we'll get it done. And I'll just put this over to the side. We're talking about in the English language at this point. Because, obviously, there is probably going to be a need at some point to deal with the Chinese language but --

THE COURT: Absolutely. I would think so.

MR. SLATER: -- we can -- that's something we can learn, hopefully, through the meet-and-confer process, to find out what documents are kept in Chinese, what are in English, et cetera, so we can figure out what it is we're asking for and what we need, when we get to that point, in terms of search terms in a foreign language.

THE COURT: Defendants, can we live with that?

MR. GOLDBERG: Yes, your Honor.

THE COURT: September 16, I'll put this in the order, defendants take the first cut at the custodians. I guess it would be for each of the responsive defendants. Plaintiffs take the first cut at search terms. I guess it would be by category, right? And then 30 days or so to give comments, meet and confer, and then we'll build in times to meet with the Court, with the goal of getting it finalized in hopefully

December, and then away you go.

MR. GOLDBERG: And this is at the API and finished dose level?

THE COURT: Yes, I think so.

I have a feeling, hopefully, that when all of this is straightened out and the dust settles, you'll say, well, we need this category of documents from the distributor or wholesaler, and you may need one or two categories, but I would hope you wouldn't need an omnibus document request from those sort of peripheral people.

MR. SLATER: Yeah. The only caveat -- you're right, your Honor, with just one caveat. We may need to come back to your Honor if we have an issue with defense, which we hope we won't. There may be certain things we need from some of the other categories of defendants that may relate to some of the economic claims, pricing, some of the class issues --

THE COURT: I agree with you. I don't disagree with you, but that's not a front burner issue right now.

MR. SLATER: When that becomes -- when we start to see those issues, we'll will talk to the defendants.

THE COURT: No, I agree with you. You'll need to do your economic model and you'll seed sales and pricing information, and that's when it will come into the forefront, but we've got enough to do before we get there.

MR. SLATER: And we're hopeful, frankly, that the

finished dose manufacturers will have most of that information, if not all of that information, anyway. Presumably, they know what the drugs are being sold for, but there may be gaps. So we'll seek it in the first instance, obviously, from them.

THE COURT: Okay. Anything else, counsel?

MR. GOLDBERG: Nothing from the defense, your Honor.

MR. SLATER: Just one last thing. The things that we said there is going to be followup, certain -- I know Mr. Goldberg gave us deadlines that he's going to produce certain things, but just overall, just in terms of some of the things that are being provided that we put on the record, I thought maybe it would make sense just to say when will that be produced by, just so it's not hanging out there.

THE COURT: Well, everything you agreed -- you started out by listing the three things you agreed on. We said that's going to be produced in 30 days.

MR. SLATER: Right.

THE COURT: And then the eCTD, I don't know how long that takes, but we'll probably do 30 days.

MR. SLATER: Frankly, your Honor, we're fine with an outside of 30 days, if the defense is fine with it.

THE COURT: Yes.

MR. SLATER: Other than I think there was a couple things that ZHP said they would give us within, you know,

about a week and a half, but other than that, as long as there is some deadline, that's fine.

THE COURT: Yes, if they agree to do it earlier, of course we're not going to object to that.

You have the extension for the document requests and the objections. We talked about custodians and search terms.

I don't think we have a call for the end of August, but if an issue comes up, we're available.

I think our next in-person meeting is the -- well, the next in-person meeting is the end of September, but we'll have a phone call, unless we need to meet in person, in mid September. And I hope everybody enjoys the rest of their summer.

RESPONSE: Thank you, your Honor.

(The proceedings concluded at 4:34 p.m.)

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

*/S/ Carol Farrell, NJ-CRCR, FCRR, RDR, CRR, RMR, CRC, CRI*
*Court Reporter/Transcriber*

*September 05, 2019*
*Date*

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